NO. 05-4474

IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

UNITED STATES

Plaintiff-Appellee,

--v.--

WILLIAM ELIOT HURWITZ

Defendant-Appellant

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA

BRIEF FOR AMICI THE AMERICAN PAIN FOUNDATION, THE NATIONAL PAIN FOUNDATION AND THE NATIONAL FOUNDATION FOR THE TREATMENT OF PAIN IN SUPPORT OF APPELLANT AND REVERSAL OF THE CONVICTION.

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CORPORATE DISCLOSURE STATEMENT

United States of America v. William Eliot Hurwitz, No. 05-4474

Pursuant to Federal Rule of Appellate Procedure 26.1, *Amici Curiae* The American Pain Foundation, the National Pain Foundation and the National Foundation for the Treatment of Pain make the following disclosure:

1) For non-governmental corporate parties please list all parent corporations:

None.

2) For non-governmental corporate parties please list all publicly held companies that hold 10% or more of the party's stock:

None.

3) If there is a publicly held corporation that is not a party to the proceeding before this Court but which has a financial interest in the outcome of the proceeding, please identify all such parties and specify the nature of the financial interest or interests:

None.

4) Amici are not trade associations.

Dated: September 8, 2005

Samuel Rosenthal

Attorney for The American Pain Foundation the National Pain Foundation and the National Foundation for the Treatment of Pain

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INTERESTS OF AMICI

Pain Care Amici are three distinct leading organizations at the national and state level representing persons with chronic intractable pain. All three Amici have an interest in making certain that their constituencies receive adequate treatment for pain which, for many of them, constitute a crippling and debilitating condition. Both parties in this appeal consent to the filing of this brief.

The American Pain Foundation is the nation's largest nonprofit organization devoted exclusively to people with chronic and acute pain. Its mission is to improve the quality of life for those with pain by raising public awareness, providing practical information, promoting research, and advocating removal of barriers to effective pain management. Its website, www.painfoundation.org, is a respected resource for patients and professionals alike. The APF Board of Directors, who endorse this brief, includes some of the most respected pain practitioners in the world, practicing at The American Cancer Society, Baylor College of Medicine, Beth Israel Medical Center, Duke Institute on Care at the End of Life, Johns Hopkins University Medical Center, M.D. Anderson Cancer Center, Sloan Kettering Medical Center and University of California at Davis Medical Center.

The National Pain Foundation addresses the pain pandemic with its comprehensive array of programs. A non-profit 501 (c)(3) organization, the NPF

works to advance the functional recovery of persons in pain through providing education, advocacy, and support. Through the coordination of information technologies, community outreach, linking people in pain with resources and education, the NPF is achieving its mission: to be a credible and highly effective resource to empower all persons in pain, regardless of race, ethnicity, religion, or economic or social status, to improve their lives through education, advocacy, communication networks, and community participation. See National Pain Foundation website, www.painconnection.org.

Finally, the National Foundation for the Treatment of Pain is a national nonprofit organization dedicated to providing emotional and educational support for patients who suffer from intractable pain, as well as the families, friends, physicians and other health professionals who help care for them. Its website, www.paincare.org, has proven a popular and important resource to this end.

SUMMARY OF ARGUMENT

Appellant, Dr. William Hurwitz, was convicted for distributing drugs to patients of his medical practice. Some of these patients admitted selling prescribed pain medicine after concealing their activities from Dr. Hurwitz. Other patients were unquestionably legitimate patients who obtained prescription drugs from Dr. Hurwitz for the sole purpose of relieving their own pain. The prosecution

claimed that the prescriptions to these patients – whether legitimate or illegitimate -- were "beyond the bounds of medical practice." Accordingly, Dr. Hurwitz's actions were criminal.

The instructions given the jury below were critically flawed in important respects. The court refused to give a good faith instruction, doing away with this court's precedent and all previous assurances that a physician who acts in good faith to treat pain, unquestionably a legitimate medical purpose, is not guilty of drug distribution. Serious misjudgment, ignorance or mistake were thought previously to allow loss or limits on medical licensure and/or DEA registration, a malpractice verdict, or even state indictment for reckless negligence. The conviction below broke ground by holding that a doctor acting in the good faith belief that he was serving the best medical interest of his patient could be found to be a drug dealer under the Controlled Substances Act (CSA). Additionally the court refused to define "the bounds of medical practice" as the jury requested, and instead gave erroneous instructions in three critical areas: the legality of prescribing drugs to a person taking them "other than as directed;" to a suspected addict or substance abuser; and the significance and degree to which "excessive doses" were administered.

If not reversed, the resulting conviction will profoundly impact both doctors and patients. It will deter physicians from treating chronic pain by

prescribing opioid medications. To assist the Court in appreciating this impact, Amici inform the Court about the difficulties of treating and accessing treatment of pain today.

Amici do not dispute that doctors should prescribe opioids "within the bounds of medicine", but the current case leaves them with no idea what the phrase means. The normal difficulty a jury would have in resolving disagreements among experts as to what constitutes "the bounds of medicine" was exacerbated because the jury sought, but was never given, a definition of that phrase, and was not permitted to consider medical consensus statements and guidelines. Nor did the trial court allow testimony that the Virginia Medical Board found Dr. Hurwitz' conduct, specifically, to be in good faith.

The decision will also discourage practitioners from accepting patients' statements about their own symptoms. It should not be a crime for a doctor, relying on the patient's information, to provide medication for the legitimate purpose of relieving pain. If it is, and there is no guidance about how a physician should "police" his patients, prudent physicians will not risk their futures by prescribing opioids.

ARGUMENT

I. PAIN AND THE NEED FOR ITS EFFECTIVE TREATMENT

Any decision curtailing access to pain medications will impact suffering patients, medical practitioners, and society burdened by medical and other costs when pain is untreated.

Chronic pain is a devastating condition. As Albert Schweitzer put it, "[p]ain is a more terrible lord than death itself."[1]

> Pain is dehumanizing. The severer the pain, the more it overshadows the patient's intelligence. All she or he can think about is pain: there is no past, no pain-free memory, no pain-free future, only the pain-filled present.[2]

Chronic pain is almost universally accompanied by anxiety and depression.[3] Patients may believe that suicide or death is the only source of relief from pain.[4]

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[1] Quoted, Stuart Davidson, *Pain and Opiophobia*, 40 Healthcare Forum, J. 64, 64 (May/June 1997)

[2] Lisson, E. L., *Ethical Issues Related to Pain Control*, 22 Nursing Clinics N. Am. 649, 654 (1987)

[3] Medical regulators are well aware of this. Pennsylvania Medical Board, *Habits of Highly Effective Pain Managers*, Newsletter, 3 (Winter 2002) www.dos.state.pa.us/bpoa/LIB/bpoa/20/10/mednews02.pdf [visited 10/30/03].

[4] Bernhoff, R., *How We Can Win the Compassion Debate*, Citizen Magazine (June 24, 1996) (noting that "patients often want to die because of undertreated pain"); Kathleen M. Foley, *The Relationship of Pain and Symptom Management to Patient Requests for Physician-Assisted Suicide*, 6 J. Pain Symptom Mgt. 289 (1991). See

Pain is not just a symptom. It is also an independent "destructive disease with physical, psychological and behavioral consequences."[5] Chronic pain compromises the immune system, slows healing and causes cell damage and death. Untreated pain "rewires" the nervous system so that even when the original cause of pain is removed, pain continues.[6] This "rewired" pain can be harder to treat than the original cause. It requires timely and effective treatment.

A. Chronic Pain is Costly to Society.

As many as 50 million Americans cannot work productively and become fully or partially disabled because of chronic pain.[7] Pain is one of the most frequent causes for Social Security disability, dramatically affects state, federal and private health care costs, and adds to state Medicaid costs. The total cost of

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also, Washington v. Glucksberg, 521 U.S. 702, 731 (1997) ("many people who request physician assisted suicide withdraw that request if their depression and pain are treated").

[5] Brookoff, D., *Chronic Pain I: A New Disease?* Hospital Practice, McGraw-Hill Companies (2000); www.hosppract.com/issues/2000/07/brook.htm [Accessed 10/28/03].

[6] *Id.* "Patients who have had uncontrolled pain for months or years often find that their pain has spread beyond the originally affected...[location]. In these cases, physicians who are not familiar with the concept of neural plasticity are apt to conclude that the pain is psychogenic, because it does not conform to their preconceived map of the nervous system."

untreated pain from lost workdays is substantial, approximating $100 billion a year.[8] Consider the following:

- 75 million people live in chronic, debilitating pain. Many have endured years of agony and undergone two or more failed surgeries seeking pain relief.
- Chronic pain accounts for more than 80 percent of all physician visits.
- Pain costs the nation an estimated $70 billion a year in medical claims, disability payments and lost productivity.

[http://www.painconnection.org/AboutUs/default.asp]

Experts estimate that most moderate to severe pain can be reduced to manageable levels. A 1999 survey revealed that only a quarter of the millions of adults experiencing long-term moderate to severe pain annually received adequate treatment. Minorities, women, the very old and the very young are the least treated, but all groups reported difficulty in obtaining adequate medical care.[9]

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[7] National Institutes of Health, *The Management of Chronic Pain*, Program Announcement PA NUMBER: PA-01-115 (July 2, 2001); http://grants1.nih.gov/grants/guide/pa-files/PA-01-115.html [accessed 10/28/03].

[8] American Pain Foundation, "Facts About Pain;" www.painfoundation.org [accessed 10/28/03].

[9] American Pain Society, "Chronic Pain in America: Roadblocks to Relief;" www.ampainsoc.org [accessed 10/10/03].

B. Opioids Can Effectively Treat Pain, But Fear of Prosecution Curtails Their Use

For many years, opioids were restricted almost entirely to treat pain in the dying because of fears of addiction or respiratory depression. In the mid-1980's peer reviewed clinical journals began emphasizing that opioids could also safely alleviate chronic pain unresponsive to other medications.[10] Medical organization and government- sponsored clinical guidelines now support and encourage opioid treatment for chronic pain.[11] Some types of pain previously thought non-responsive to opioids now appear responsive with more aggressive dosing.

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[10] Portenoy *et. al,* Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 Cases, *PAIN*, Vol. 25, 171-186, (1986).

[11] "The Use of Opioids to Treat Chronic Pain: A Consensus Statement of the American Pain Society and the American Society of Addiction Medicine (1996). ("Consensus Statement);" http://www.ampainsoc.org/advocacy/opioids.htm [Accessed 10/25/03]. See, also *e.g.,* American Geriatric Society, Guidelines for Opioid APS/AAPM, AGS etc. A full list of guidelines can be found in Pain: Current Understanding of Assessment, Management, and Treatments, National Pharmaceutical Council & The Joint Commission on Accreditation of HealthCare Organizations (JCAHO), 75, (December, 2001). In 2001, JCAHO mandated pain assessment and management in all accredited hospitals and nursing homes.

Experience shows that patients rarely become addicted to prescribed opioids.[12] Also respiratory depression, even extremely high levels, does not occur in the context of appropriate clinical treatment. Opioids also causes no organ damage. Hence there is no "ceiling dose" and clinicians are urged to individualize dosage levels based on their effect since therapeutic levels vary widely among patients.[13] More than twenty States have enacted statutes protecting a patient's right to be informed of, and treated with, opioids. See, e.g., Florida Intractable Pain Act, F.S.A. §458.326 (1994) (Florida law and policy assures doctors that treating chronic pain with opioids is permissible). See also Va. Code Ann. § 54.1-3408.1 (2004) (protecting doctors who in good faith prescribe high doses of opioids).

Fear of criminal or regulatory sanction is a major reason for physician's failure to treat pain using opioids.[14] The physicians fear that drug diversion or abuse by a deceptive patient will result in their prosecution.

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[12] Portenoy, Russell, et al., *Acute and Chronic Pain*, *in* COMPREHENSIVE TEXTBOOK OF SUBSTANCE ABUSE 863-903 (Lowinson et al. eds., 4th ed. 2005).

[13] A textbook edited by the Government's own expert states that dose is titrated either until the pain is improved or intolerable side effects develop. Ashburn and Rice, "The Management of Pain," Ch. 8, "Nonopioid and Opioid Analgesics," by Zuckerman and Ferrante, at 112, Churchill Lvingstone, (1998).

[14] See, Portenoy R., *Opioid Therapy for Chronic Nonmalignant Pain: Clinicians' Perspective*, 24 J.L., Med., & Ethics 296, 297 (1996); American Society of Addiction Medicine Position Statement (April 1997) ("[P]hysicians' concerns

Their fears are shared. In January 2005, thirty state attorneys general wrote to the DEA Administrator, advising "adequate pain management is often difficult to obtain because many physicians fear investigations and enforcement actions if they prescribe adequate levels of opioids or have many patients with prescriptions for pain medications."[15] They objected to DEA policy shift from a balanced approach to emphasis on prosecution. They warned that this change "seems likely to have a chilling effect on physicians engaged in the legitimate practice of medicine." [Id.]. The Attorneys General reiterated their concern in a

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regarding possible . . . sanctions related to the prescription of opioids contribute significantly to the undertreatment of pain."); Joranson, D., Gilson, A., *Controlled Substances, Medical Practice, and the Law*, in Psychiatric Practice Under Fire 188 (H. Schwartz ed., 1994); Shapiro, supra note 1, at 363 (noting "fear of legal penalties, especially disciplinary action," as important reason for under-treatment of pain); *Undertreatment of Pain Seen as Unintended Effect of Drug War*, 9 Alcoholism and Drug Abuse Week 1 (June 23, 1997); Davidson, supra note 5, at 64-67; Sandra H. Johnson, Disciplinary Actions and Pain Relief: Analysis of the Pain Relief Act, 24 J.L., Med., & Ethics 319, 320 (1996); Shannon Brownlee & Joannie Schrof, The Quality of Mercy, U.S. News & World Rep. 54, 56 (March 17, 1997) (noting doctors' fear of prosecution); Russell K. Portenoy and Richard Payne, Acute and Chronic Pain, in Substance Abuse, A Comprehensive Textbook 563, 582-84 (Joyce H. Lowinson et al. eds., 1997) [hereinafter "Comprehensive Textbook"]. See also Chris Hyman, Pain Management and Disciplinary Action: How Medical Boards Can Remove Barriers to Effective Treatment, 24 J.L., Med., & Ethics 338, 338 (1996).

[15] www.painreliefnetwork.org/ painreliefnetwork/file_uploads/NAAGletter.pdf (accessed September 2, 2005)

formal submission in March, 2005.[16] Affirmation here will further erode the willingness of doctors to properly treat patients in desperate need of care for chronic and debilitating conditions. Without clear-cut guidance for doctors on what constitutes a criminal violation, patients and society will suffer.

II. THE JURY CHARGE BELOW REQUIRES REVERSAL AS IT IS FUNDAMENTALLY AT ODDS WITH ANY REASONABLE STATUTORY CONSTRUCTION

Dr. Hurwitz was convicted under, inter alia, 21 U.S.C. Sec. 841(a)(1), which prohibits the prescription of drugs "outside the bounds of [a doctor's medical practice]." United States v. Tran Trong Cuong, 18 F.3d 1132, 1137 (4th Cir., 1994)(emphasis added)." See also United States v. Moore, 423 U.S. 122 (1975); (acquittal required where a physician acted "in good faith"). The trial court's instruction to the jury was contrary to any rational construction of the statute or the phrase "outside the bounds of medicine."

Until this case, doctors were assured that they were practicing "outside" or "beyond the bounds of medical practice" when they "prescribe[d] controlled substances . . . not for treatment of a patient, but for the purpose of assisting another in the maintenance of a drug habit or of dispensing controlled substances for other than a legitimate medical purpose . . ." Tran Trong Cuong,

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[16] Text link to letter accessed at www.doctordeluca.com/Library/WOD/WpsBillings/Billings-PainPtsGetMythOfRx05.htm (September 2, 2005).

18 F.3d at 1138 (emphasis added). It was settled law that if "[a] doctor dispenses a drug in good faith in medically treating a patient, then the doctor has dispensed the drug for a legitimate medical purpose in the usual course of medical practice...," and that if the doctor "acted in good faith in dispensing the drug, then [a jury] must find him not guilty [of illegally diverting drugs]." Id. (approving use of the foregoing jury instructions).

The jury instructions here grossly depart from this precedent. The trial court instructed the jury that it could convict even if it found the doctor's actions consistent with a "legitimate medical purpose," but he was acting "outside the bounds of medicine." See, e.g., J.A. 4752 (prosecution's closing argument in which the jury was told: "All [the jury instructions] require is Dr. Hurwitz went 'outside the bounds of medicine.' They could be legitimate patients, but he went outside the bounds of medicine . . . "). Following those instructions, the jury convicted Dr. Hurwitz of prescribing to patients, including those whom the prosecution conceded to be unquestionably in pain and in need of treatment, and who never sold the drugs or used them other than as directed.[17] Thus, according to the judge's instructions, a doctor can now be convicted if he or she prescribes drugs for a legitimate medical purpose, and in good faith.

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[17] A centerpiece of the Government's case was patient Linda Lalmond, who the Government contends died from a drug overdose. There was no evidence that she

These jury instructions are likely to dissuade the medical community from using sound medical judgment in treating pain patients. Practitioners are instead likely to forgo the use of opioids or other drugs.

A. The Trial Court's Instructions Are Particularly Disturbing in Light of the Physician's Duty to Treat Pain.

The prosecution in this case depicted Dr. Hurwitz as an ordinary drug dealer. See, e.g., J.A.1275-76. However, the distinction between a doctor treating pain and a drug dealer could not be greater. A drug dealer has no right, duty or legitimate reason for providing narcotics to another person. Absent a prescription, non-medical personnel do not even have the legal right to possess narcotics.

By contrast, doctors are professionally, legally, and ethically obligated to prescribe medications, including controlled substances, to a patient when needed for a medical purpose. This distinction between a drug dealer and a doctor treating pain has been made dramatically clear by cases holding doctors criminally responsible for failing to prescribe narcotics to patients in pain, and in need of medical care. See, e.g., Bergman v. Chin, No. H2057321, 2001 WL 1517376 (Alameda County Superior Court, June 13, 2001; see also Tomlinson v. Bayberry Care, No.C 02-00120 (Cal. Sup. Ct. Contra Costa County 2003). Even without those decisions, professional and ethical standards require doctors to treat pain,

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was addicted to drugs. The Government's theory was that Dr. Hurwitz prescribed an excessive quantity of opioids.

including, where appropriate, treatment with opioids. See, e.g., Letter from State Attorneys General to DEA, http://www.naag.org/issues/pdf/20050321-final-DEA-comment.pdf ("The undertreatment of pain is a significant problem and led the Federation of State Medical Boards (FSMB), in 2004, to promulgate new model policy to emphasize that undertreatment of pain, like overtreatment, constitutes poor practice....").

B. The Conviction Below – And the Refusal to Allow the Jury to Consider a Doctor's Good Faith -- Contrasts Starkly With the Legal, Regulatory and Professional Framework of Medical Practice.

Because doctors are required to treat pain, criminal rules must allow them to act in what they believe to be the best interests of their patients. Because doctors are trained in medicine; not law, the judicial system should remove inconsistencies and internal conflicts that make it impossible to practice medicine without a "subspecialty" in criminal law. The conviction below does precisely the opposite by introducing internally contradictory pressures that pit federal and state laws against each other. The result is a high-stakes guessing game requiring physicians to test medical judgment against perceptions of personal risk and responsibility rather than medical guidelines and ethical precepts.

Doctors have long been assured that they would not be criminally prosecuted for drug dealing if they prescribed medications in the good faith belief

that they were medically appropriate. Virginia, where Dr. Hurwitz practiced, protected a physician acting "in good faith for accepted medicinal or therapeutic purposes " from being prosecuted for prescribing excess dosages. Va. Code Ann. § 54.1-3408.1 (2004), See also Va. Code Ann. § 54.1-2971.01 (2004) (§ 54.1-2971.01.) The DEA, in countless presentations to medical audiences promised the same.[18] Even as the trial below was proceeding, DEA Director Karen Tandy assured doctors that they would not be prosecuted if they acted in good faith in prescribing opioids. See Letter to the Editor from Karen Tandy, USA Today, 12/7/04, quoted in www.baltimorechronicle.com/021405Richman.shtml.

In light of these provisions and assurances, Dr. Hurwitz sought simply to have the jury told that it should consider his good faith. J.A.719, J.A.4909. The lower court refused. The refusal was particularly troublesome because not only did the Virginia statute expressly decline to criminalize good faith prescribing of opioids, but the Virginia Board of Medicine had found that Dr. Hurwitz was acting in good faith. J.A.285.

In fact, the Court willingly gave a good faith instruction on filing false insurance claims, see J.A.4909 (insurance fraud charged in Counts 61 and 62), while refusing it in the distribution-related counts. The court even acknowledged

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[18] See, e.g., Patricia M. Good , Chief of the Liaison and Policy Section of the Drug Enforcement Administration's Office of Diversion Control, Address at the

that this contradictory approach would likely confuse the jury, as both charges involved the very same prescriptions, rendered to the very same patients. See J.A.127-28; J.A.131-32. Significantly, the jury acquitted Dr. Hurwitz on those counts, where good faith was charged.

Doctors must conclude that their good faith beliefs about the best medical interests of the patient may be irrelevant, and that their conduct will be judged on some vague notion, often at odds with consensus view of other medical practitioners, that their conduct is "beyond the bounds of medicine." Many practitioners will resolve that dilemma by refusing to prescribe opioids when needed, and may refrain from pain management entirely.

C. The Court Compounded Its Error Regarding Good Faith By Refusing to Define the "Bounds of Medicine."

It was reversible error to require the jury to determine whether Dr. Hurwitz exceeded the "bounds of medicine" without defining that term or telling the jury how to resolve conflicting prosecution and defense expert testimony. It failed to instruct the jury regarding state or federal rules, regulations, community standards, or the consensus statements of medical societies. Instead of requiring mens rea, the court made guilt or innocence depend on whether Dr. Hurwitz' conduct was consistent with anecdotal evidence from various doctors testifying

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Federation of State Medical Boards Symposium on Pain Management and State Regulatory Policy (Mar. 17, 1998).

about their own particular practices. It allowed a finding of guilt based on departure from standards deemed appropriate by the particular doctors selected to testify, not the medical profession or community, or any regulatory body.

The "bounds of medicine" was central to this case, as the judge's instructions reflect, see J.A.4901, and the prosecutor's opening and closing emphasized. See J.A.1291-94; J.A.4766-67. The jury heard no testimony explaining this phrase, and the judge's initial instructions failed to offer any guidance whatsoever on its meaning. Not surprisingly, during deliberation the jury asked the judge to define the "bounds of medicine" as they relate to prescribing opioids to an addict the Court responded:

> Whether the physician thinks suspects or knows that the patient is addicted to illicit drugs is a circumstance you may consider in determining whether the prescription of opioids to that patient is not for a legitimate medical purpose or beyond the bounds of medical practice.
>
> For example, if the physician knew, as defined in the charge on page 11, that the addicted patient would be distributing the prescribed substance to others or that the patient would be abusing the prescribed substance by taking contrary to the directions for use, then it would be prescribed not for a legitimate purpose and beyond the bounds of medical practice. "

While reminding the jury that it was insufficient that the doctor was "merely negligent in not discovering the truth," J.A.4929, this instruction was fatally flawed as inconsistent with either the facts or the law.

The prosecution expert, Dr. Ashburn, identified no professional guidance, legal definition or other authoritative standard for determining what constitutes the "bounds of medicine." Instead, he was told by the prosecution to create three circles: an inner circle representing ideal care, the next outer circle representing malpractice, and the third representing practice outside the bounds of medicine. J.A.2601. In short, Dr. Ashburn equated conduct outside the "bounds of medicine," with something more than normal malpractice, but the judge did not instruct on malpractice or guide the jury in evaluating whether it was exceeded.

The prosecution's second expert, Dr. Hamill-Ruth, was never asked to define the "bounds of medicine." She testified at length about the practices followed in her clinic, including practices used where a patient obtained drugs (legal or illegal) elsewhere:

> If the patient is positive for multiple, multiple medications that we are not prescribing, then we'll generally just cut them off, because I'm assuming they have enough other suppliers that they're not going to withdraw if I don't provide.

J.A.3347. Dr. Hamill-Ruth admitted that her approach reflected her busy practice, not professional norms. See J.A.3347 ("We're at the point where we're so busy

that we just discharge them if they don't play ball"). However, "if [a patient abusing medicine] had a very severe pain problem and I was feeling kind, then I would potentially offer them non-narcotic therapies". J.A. 3349. Dr. Hamill-Ruth never testified that other doctors engaged in the same "assumptions," or based treatment decisions whether she "was feeling kind," or followed her particular approach in any other respect. Nor did she testify that her practices were consistent with any medical consensus.

Instead of clarifying "the bounds of medicine," the instructions left the term wide-open, and not dependent upon any particular state or federal law, regulation or even professional guideline. The only lesson for physicians from this case is that the practice of pain medicine carries a high risk that a doctor's conduct will be found to exceed some amorphous standard. The ultimate result will be fewer doctors willing to engage in an already neglected area of practice.

D. There Was No Basis For Arguing to the Jury that Specific Conduct Fell Outside the "Bounds of Medicine"

Instead of defining the "bounds of medicine," the court allowed the prosecution to substitute three examples of conduct that fell "outside the bounds of medicine," namely that Dr. Hurwitz prescribed opioids: (1) to patients whom he should have known were using drugs "other than as directed;" (2) at dosages that were too high, and/or (3) to persons he should have "suspected" were addicted to drugs or engaging in diversion. Other than this conduct, the prosecution offered no

other basis for finding that Dr. Hurwitz' conduct exceeded the "bounds of medicine." However, as explained below, the theory of the prosecution rested on its own highly debatable view as to the wisdom or propriety of particular treatment protocols, rather than any properly promulgated rule or law. In fact, as also explained below, the prosecution view as to appropriate health care did not even represent a consensus view among doctors about sound medical practice, and conflicted with testimony of its own expert in at least one instance.

1. There Was No Basis for Finding Criminal Conduct If A Doctor "Suspects" a Patient of Taking Prescription Drugs "Other than As Directed."

The court instructed the jury that if Dr. Hurwitz knew that the "patient would be abusing the prescribed substance by taking contrary to the directions for use, then it would be prescribed not for a legitimate purpose and beyond the bounds of medical practice. " J.A.4928. No witness provided any legal, factual or ethical basis for this instruction. In fact, formal guidelines reflect that patients sometimes unilaterally increase their medications or seek other sources for opioids, precisely because they have been unable to achieve satisfactory pain relief.[19] A doctor who acknowledges that situation should not be declared a "drug dealer."

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[19] Pain may persist because physicians either do not prescribe opioids or provide an ineffectively low dose. While no one condones using illegal drugs as a self-help remedy, many physicians properly believe that the appropriate response is to find an effective medical regime, rather than cutting the patient off from needed medication, thereby ensuring that he or she will continue to obtain drugs illegally.

The jury instruction even conflicts with testimony of the prosecution's own witness as to her own practices. She testified that if she has a "metastatic cancer patient who is inadequately treated, if they take extra medication, I'm certainly not going to fault them for that. . . " J.A.3373. Nor would other health care practitioners.[20] Nevertheless, under the judge's instruction, this government expert would be would be guilty of drug dealing.

Nor could Dr. Ashburn properly identify any medical standards in testifying that it is outside the bounds of medicine to prescribe opioids to anyone who broke his rules. He erroneously testified that his positions were consistent with the Virginia Medical Board Guidelines for Prescribing Opioids. The Guidelines do not even address the question of prescribing to an abuser and are permissive about prescribing after a patient violates boundaries established in the "patient contract."

See, e.g., Definitions, Federation of State Medical Boards, Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (1998) http://www.medsch.wisc.edu/painpolicy/domestic/model.htm (accessed September 2, 2005).

[20] Even where a non-cancer patient was concerned, Dr. Ruth-Hamill testified that she would expect that a patient would call the doctor "to increase their medication. . . .," but never suggested that she would turn the patient out on the street, or that she would consider it "drug dealing" to continue treating that patient. J.A.3373.

2. Prosecution Testimony About High Dosages of Opioid Does Not Represent the Prevailing View in the Medical Community and Fundamentally Contaminated the Jury's Ability to Discern Conduct "Outside the Bounds"

A centerpiece of the prosecution case was that Dr. Hurwitz prescribed opioids in such excessive doses as to be outside the bounds of medical practice. Relying on Dr. Ashburn's testimony the prosecution argued that any dosage over 195 milligrams of morphine per day was excessive, and thus "outside the bounds of medicine:" J.A.4766. Lacking definition of the term, the jury could not have avoided considering high doses the equivalent of criminality.

No consensus in the medical community supports this view. The notion that dosages of morphine in excess of 195 milligrams per day is excessive, has been criticized as "absurd."[21] Dr. Ashburn's testimony is stunning in light of a textbook which he co-edited, which states that "[t]here is no predetermined maximum dose of an opioid." It states also that "doses of opioids should be

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[21] Six past presidents of the American Pain Society, an association that Dr. Ashburn also served as president wrote (J.A.752) to defense counsel –

> Dr. Ashburn asserts (page 23 of the transcript) that morphine at a dose of 195 mg/day constitutes a high dose. This statement is without foundation in the medical literature and we believe that it is, on its face, absurd.

escalated until pain relief occurs or side effects intervene." Ashburn et al., The Management of Pain, supra, Ch. 8 at 132.

Federal law contains no dosage limit for opioids.[22] In fact, the DEA refused in 1998 to address either the selection or quantities of drugs prescribed by a doctor, as those were "medical decisions [that] arise from the prescribing physician's medical judgment." "The DEA Proposed Model Guidelines for the Use of Controlled Substances in Pain Management," http://medsch.wisc.edu/painpolicy/domestic/dea98.htm, at 2. Virginia statutorily rejects "excessive dosages" as a basis for regulatory sanction.

Nor is there even the slightest consensus on other points made by the prosecution and its expert, including statements that opioid treatment of a patient with a known addiction is medically wrong and worsens the addiction; that high dose opioids produce hyperalgesia (increased pain), respiratory depression and compromise the immune system. See J.A.2469-70. Hyperalgesia at high doses of opioids, at best, is a theoretical concern still debated. The medical community agrees that respiratory depression poses no risk for patients taking medications as prescribed.[23] There is far more clinical journal authority that untreated pain negatively affects the immune system than as exists for Ashburn's position.

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[22] Larry Houck, *The Drug Enforcement Administration, Controlled Substances and Pain Management*, Special OxyContin® Issue, Volume 01.

Emphasis on dosage amounts has been strongly criticized by thirty-two State Attorneys General in March, 2005. They condemned the DEA's , emphasizing, inter alia, the "number of tablets prescribed for each patient" in determining whether a doctor's practice is drug diversion.

> The undertreatment of pain is a significant problem and led the Federation of State Medical Boards (FSMB), in 2004, to promulgate new model policy to emphasize that undertreatment of pain, like overtreatment, constitutes poor practice. ... Because good practice may involve precisely the factors that DEA believes might be indicative of diversion, DEA is creating a climate that puts legitimate medical practitioners in danger of investigation and discourages good practice.

It is preposterous to believe that a lay jury can decide issues such as how dose levels affect evaluation of "beyond the bounds of medicine", particularly when that term is left undefined.

3. It is Not Drug Dealing to Prescribe Opioids to Patients That Might be "Suspected" Addicts or Substance Abusers.

Not only did the court instruct the jury that continued treatment of patients with any form of prescription misuse was tantamount to drug dealing, the prosecution continually stressed that some of Dr. Hurwitz's patients were drug abusers, and should have been terminated. The jury was instructed that if Dr.

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[23] Fohr, S., *The double effect of pain medication: separating myth from reality*. J. Palliative Medicine. 1998; 1:315-26; Consensus Statement, *supra* note 14, at 2.

Hurwitz merely "suspect[ed] that a patient [was] addicted to illicit drugs . . ." that was a circumstance that the jury should consider in determining whether Dr. Hurwitz was practicing "outside the bounds of medical practice." J.A.4928. Once again, no regulation, professional or community norm was offered against which the jury could assess Dr. Hurwitz's conduct. Nor was the jury told that a medical consensus believes that opioids may be used to treat a substances abuser in serious pain and that doctors who do so do not exceed the "bounds of medicine" unless there is " [i]ncontrovertible evidence of criminal activity, such as diversion . . . ." J.A.363-64.

As a preliminary matter, one of the biggest problems affecting any determination of what a doctor knew or "suspected" is lay confusion over "tolerance", "addiction" and "drug dependence". In the lay world, concepts of dependence or tolerance are often used to define "addiction". In medical terms, however, they are very different. Physical dependence is a physiological state that inevitably develops with long-term opioid use. If one is physiologically tolerant, abrupt termination or rapid dose reduction will cause withdrawal."[24] Dependence is usually accompanied by " tolerance" to a given level of medication so that one requires higher dosages over time to produce the same effect.[25] Thus an unguided

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[24] Id.

[25] Id.

lay jury might view increased use of a substance (tolerance) that one cannot just stop taking (dependence) as "addiction." Medically, however, addiction is a "primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations."[26] An addict will develop a dependence and demonstrate a tolerance to drugs but he will also compulsively seek out the drug despite terrible harm to him and his family. This latter element is crucial to defining addiction.

The jury instructions required the jury to evaluate a "suspicion" of addiction. They gave absolutely no basis for determining what addiction is. More importantly they failed to address what ethical or professional norms govern treatment of pain in a person addicted to or abusing narcotics.

Instead, the prosecution argued that Dr. Hurwitz ignored "red flags" indicative of substance abuse. The ranged from "track marks or ulcers" to "a chaotic home life". See J.A.4761-62. Amici accept that doctors should, when practicable, consider "red-flag" factors in determining appropriate treatment. It is a far cry, however, to conclude that a doctor is acting criminally by continuing to prescribe drugs, including opioids, to a patient where one or more red flags is present. In fact, there is a serious debate over whether it is even ethical to withhold

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[26] Id.

pain treatment from known addicts, much less what to do where there is only a suspicion of addiction or diversion.

The prosecution's own expert admitted that no consensus existed. See J.A.3362 (answering "I would guess so," when asked whether there is a debate occurring over whether to treat patients who has had past drug problems, and that some clinicians take the position that such patients are entitled to treatment). She even confirmed that there was a debate as to what to do with pain patients "who show current signs of drug abuse." See J.A.3372.[27]

The lack of any consensus supporting the prosecution is evident given the DEA's own published positions. Beginning in 2001, the DEA and the medical community developed a joint statement regarding treatment of those suspected or known to have abused drugs. In August 2004, that group published its conclusions on DEA's Office of Diversion Control Web Site. See Fed. Reg. Vol. 69, No. 220 (Nov. 16, 2004). There, the DEA and medical practitioners opined that it was legal to treat drug abusers:

> Federal drug laws do not require physicians to report to law enforcement authorities patients who have engaged in drug abuse. The controlling federal legal standard is

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[27] The only time that Dr. Hamill-Ruth testified that there was "no debate" in how to treat a patient was where the doctor learned that the patient was selling the drugs. See J.A.3374. The court's instructions allowed the jury to convict Dr. Hurwitz even if he did not know such facts, and the patient was simply taking the drugs other than as directed.

> that the physician must issue prescriptions for controlled substances only for legitimate medical purposes and in the usual course of professional practice. . . .
>
> In states with no specific legal requirements on this subject, if continued opioid therapy makes medical sense, then the therapy may be continued, even if drug abuse has occurred. Additional monitoring and oversight of patients who have experienced such an episode is recommended . . . .

J.A.363-64. The document added: "[I]t is within the scope of current federal law to prescribe opioids for pain to patients with a history of substance abuse or addiction. . .," and that "termination of the doctor-patient relationship was appropriate when there was "[i]ncontrovertible evidence of criminal activity, such as diversion . . . ." J.A.364.

On November 16, 2004, in response to Dr. Hurwitz's efforts to introduce the DEA's expressed policy regarding prescribing to abusers, the DEA withdrew its statement, stating that "further discussion of the subject is warranted. . . ." Fed. Reg. Vol. 69, No. 220, at 67171. This certainly did not constitute a consensus. Nor did it prevent professional groups from adhering to the "guidance" contained in the earlier announcement. The American Academy of Pain Medicine, the American Pain Society, and the American Society of Addiction Medicine, responded by acknowledging that while doctors should make an effort to be aware of red flags, "a physician must recognize that federal regulations do not preclude the treatment of pain with opioids in a patient with the disease of

addiction." [28] The AMA recommended that a doctor "not withdraw opioids from someone in acute pain, but consider addiction intervention/counseling when pain [was] controlled."[29]

The jury instructions at issue went beyond any rule even the DEA had urged practitioners to follow. While the DEA had warned against prescribing opioids "with knowledge" that they would be used for a "non-medical purpose" or "incontrovertible evidence" that they would be resold, the judge instructed that Dr. Hurwitz needed only to "suspect" drug addiction or that the patient was "taking contrary to the directions for use . . . ." In the absence of clear prohibition, it is reversible error and a precedent bound to encourage poor treatment for future patients to instruct that the disease of addiction, or mere suspicion of it, should deny patients with pain the possibility of relief through careful opioid therapy. If this conviction is upheld, doctors will no longer use medical judgment to prescribe opioids (if this is what the patient requires for pain) for fear of criminal prosecution.

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[28] http://www.painreliefnetwork.org/what_they_say.html (accessed September 2, 2005)..html.

[29] http://www.ama-cmeonline.com/pain_mgmt/module04/pop/up/table02

E. The Medical Community Should Not be Forced to Depend on Ad Hoc Decision-Making by Jurors in Criminal Cases to Define the "Bounds Of Medicine."

With particular conditions such as stroke, heart attack or diabetes, very specific treatment protocols are developed and published within the medical profession. However, pain arises from many different injuries and diseases. Because pain is subjective and felt differently by each patient, treatment should be tailored to the individual. [30]

The prosecution ignored established reality of pain treatment, and erroneously assumed that defined rules apply to every patient. However, in speaking to professional groups the DEA has taken a different position:

> The CSA does not address medical treatment issues such as selection or quantity of the drug prescribed. Such medical decisions arise from the prescribing physician's medical judgment. ...[A] physician's medical judgment is the first step in determining the appropriate course of action in the treatment of pain. This judgment must be based upon professional training, medical specialty and practice guidelines. That judgment, in concert with the establishment of a bona fide physician-patient relationship, which includes thorough examination of the patient, a review of the patient's medical history, and proper follow-up and monitoring, combine to constitute legitimate medical practice.[31]

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[30] Consensus Statement, VII. Treatment Plan.

[31] Patricia M. Good Address, supra.

This conviction will destroy the willingness of practitioners to treat patients' individual needs. If a lay jury – not the medical community -- determines the "bounds of medicine" based on anecdotal evidence of chosen practitioners, physicians will rightly assume that using medical judgment is dangerous indeed. Given a jury's lack of expertise, resources and all the additional constraints imposed on the jury system, it is preposterous to conclude that a jury in a criminal case can define particular prescriptions as "outside the bounds" when regulatory agencies and the guidelines and consensus of professional experts has not.

CONCLUSION

The Court should reverse the conviction, which will seriously undermine pain medicine. The conviction defines drug dealing without regard to a doctors' good faith, and in a manner that criminalizes practices believed by doctors to be sound, legitimate and ethically appropriate. While Amici support prosecution of unscrupulous doctors seeking to profit illegally from their profession, the conviction here went far beyond that objective.

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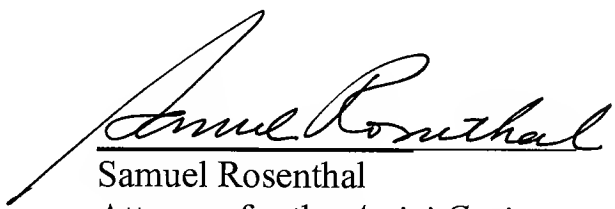

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